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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,831	12/30/2003	Richard L. Boyd	NOR-016CP2 and 286336.155	2793

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	04/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/748,831	BOYD, RICHARD L.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006 and 18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34,36-43,45-63,65-74,76-78,81 and 83-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34, 36-43, 45-63, 65-74, 76-78, 81, 83-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed on 12/20/06 and 9/18/06 were entered.

Claims 1-34, 36-43, 45-63, 65-74, 76-78, 81 and newly added claims 83-88 are pending in the present application.

Upon further consideration, the pending claims are further restricted as follows.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 9-13, 19-26, 54-59, 65-67, 69-74, 76-78 and 85, drawn to a method for genetically altering a subject having a T cell disorder caused by HIV infection or a patient infected with HIV comprising the step of administering genetically modified cells selected from the recited Markush group, a method for treating or preventing infection of a patient by HIV comprising the steps of T cell ablation, disruption of sex steroid mediated signaling to the thymus and administration of genetically modified cells in the recited Markush group, classified in class 424, subclass 93.21.

II. Claims 81 and 83, drawn to a method for enhancing transplantation of donor hematopoietic stem cells or exogenous cells into the thymus of a recipient patient comprising the steps of reactivating the thymus of the patient, and transplanting donor hematopoietic stem cells or exogenous cells to the patient, classified in class 424, subclass 93.1.

III. Claims 9, 84 and 86, drawn to a method for genetically altering a subject with a T cell disorder caused by T cell functional disorder, a method for treating a T cell disease or disorder in a patient using cells genetically modified to express a normal version of a defective gene that exists in a patient and a method for treating a patient with a genetic defect in a T cell or dendritic cell comprising reactivating the thymus of the patient, and administering autologous HSC that have been genetically modified to correct the genetic defect in the T cell or dendritic cells wherein the genetically modified HSC diffentiate into T cells or dendritic cells expressing the normal gene in the reactivated thymus of the patient, classified in class 424, subclass 93.21.

IV. Claim 54, drawn to a method for genetically altering a patient infected with Picornaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

V. Claim 54, drawn to a method for genetically altering a patient infected with Calciviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

VI. Claim 54, drawn to a method for genetically altering a patient infected with Togaviridae comprising the steps of reactivating the thymus of the patient

and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

VII. Claim 54, drawn to a method for genetically altering a patient infected with Flaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

VIII. Claim 54, drawn to a method for genetically altering a patient infected with Coronaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

IX. Claim 54, drawn to a method for genetically altering a patient infected with Rhabdoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

X. Claim 54, drawn to a method for genetically altering a patient infected with Filoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XI. Claim 54, drawn to a method for genetically altering a patient infected with Paramyxoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XII. Claim 54, drawn to a method for genetically altering a patient infected with Orthomyxoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XIII. Claim 54, drawn to a method for genetically altering a patient infected with Bungaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XIV. Claim 54, drawn to a method for genetically altering a patient infected with Arenaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XV. Claim 54, drawn to a method for genetically altering a patient infected with Reoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XVI. Claim 54, drawn to a method for genetically altering a patient infected with Birnaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XVII. Claim 54, drawn to a method for genetically altering a patient infected with Hepadnaviridae comprising the steps of reactivating the thymus of the

patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XVIII. Claim 54, drawn to a method for genetically altering a patient infected with Parvoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XIX. Claim 54, drawn to a method for genetically altering a patient infected with Papovaviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XX. Claim 54, drawn to a method for genetically altering a patient infected with Adenoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XXI. Claim 54, drawn to a method for genetically altering a patient infected with Herpesviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XXII. Claim 54, drawn to a method for genetically altering a patient infected with Poxviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

XXIII. Claim 54, drawn to a method for genetically altering a patient infected with Iridoviridae comprising the steps of reactivating the thymus of the patient and administering genetically modified cells selected from the recited Markush group, classified in class 424, subclass 93.21.

Claims **1-8, 14-18, 27-34, 36-43, 45-53, 60-63, 83** (containing the embodiment of administering genetically modified cells to the patient) and **87-88** link a plurality of distinct inventions of Groups I and III-XXIII, drawn to methods for genetically altering a variety of distinct patients in Group I, III-XXIII comprising the step of administering to the patient selected genetically modified cells. The methods of Groups I and III-XXIII are distinct methods having distinct starting materials, for example at least distinct groups of patients such as patients infected with HIV, patients having a T cell disorder caused by T cell functional disorder that requires a normal version of a defective gene, as well as patients being infected with distinct groups of viruses that cause distinct diseases (see at least the instant specification on page 28). Therefore, these distinct methods would require different technical considerations for attaining the desired end-results contemplated by Applicant.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or

divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III-XXIII are drawn to distinct methods having different starting materials that require different technical considerations for achieving the desired end-results as already discussed in the above paragraph.

Invention II is distinct from any method in Groups I and III-XXIII because it does not require the administration of any genetically modified cells to a patient while the other methods do.

Because these inventions are distinct for the reasons given above, and separate search requirements due to the distinctness of each Invention as discussed above in both **patented and non-patented literature**. It would be unduly burdensome for the examiner to **search and/or consider the patentability** (examination) of all the inventions in a single application. Accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

Should Applicants elect any one invention in Groups I-XXIII, this application contains claims directed to the following patentably distinct species of disruption of sex-steroid-mediated signaling to the thymus to reactivate the thymus of the claimed invention:

1. surgical castration and 2. chemical castration; and 3. administration of one or more pharmaceuticals.

The species are independent or distinct because a surgical castration, a chemical castration and the administration of one or more pharmaceuticals are distinct processes utilizing different techniques and materials.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 19, 27, 41, 65, 72 and 83-86 are generic.

Additionally, should Applicants elect the species 3 above, this application contains claims directed to the following patentably distinct species of a pharmaceutical of the claimed invention:

a. LHRH agonists; b. LHRH antagonists; c. anti-LHRH vaccines; d. anti-androgens; e. anti-estrogens; f. SERMs; g. SARMs; h. SPRMs; i. ERDs; j. aromatase inhibitors; k. anti-progestogens; l. Dioxalan derivatives; or m. a specific combination of species a-l.

The species are independent or distinct because each pharmaceutical is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 17, 19, 25, 27, 41, 49-50, 65, 72 and 83-86 are generic.

(i) Additionally, should Applicants elect the a species containing LHRH agonists, this application contains claims directed to the following patentably distinct species of LHRH agonists of the claimed invention:

A specific named LHRH agonist or a specific combination of LHRH agonists recited in the Markush group of claim 51.

The species are independent or distinct because each recited LHRH agonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, at least claims 1, 17-19, 25-27, 41, 49-51, 65 , 72 and 83-86 are generic.

(ii) Additionally, should Applicants elect the a species containing LHRH antagonists, this application contains claims directed to the following patentably distinct species of LHRH antagonists of the claimed invention:

A specific named LHRH antagonist or a specific combination of LHRH antagonists recited in the Markush group of claim 52.

The species are independent or distinct because each recited LHRH antagonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 17, 19, 25, 27, 41, 49-50, 52, 65, 72 and 83-86 are generic.

This application contains claims directed to the following patentably distinct species of genetically modified cells to the patient of the claimed invention:

A specific named genetically modifying cells or a specific combination of genetically modifying cells recited in the Markush group of claim 1.

The species are independent or distinct because each recited genetically modifying cell type is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, at least claims 1,19, 27, 65, 72 and 83-86 are generic.

This application contains claims directed to the following patentably distinct cytokine species, growth factor species or combination of cytokine and growth factor species:

A single specific named cytokine species <u>or</u> a single specific named growth factor <u>or</u> a single specific combination a cytokine and a growth factor recited in claims 61-63.

The species are independent or distinct because each recited cytokine, growth factor is structurally and biochemically distinct one from the others; and therefore each specific combination of a cytokine and a growth factor is also distinct from other combinations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 27 and 61 are generic.

<u>Additionally, should Applicants elect the invention of Group I</u>, this application contains claims directed to the following patentably distinct species of a polynucleotide expressible in genetically modifying cells in the claimed invention:

(a) nef transcription factor gene; (b) a gene that codes for a ribozyme that cuts HIV tat; (c) a gene that codes for a ribozyme that cuts rev gene; (d) a

ribozyme that cuts HIV tat and rev genes; (e) RevM10; (f) HIV-1 rev-responsibe element; (g) CXCR4; and (h) PolyTAR.

The species are independent or distinct because each polynucletoide is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 9-13, 19-21, 27, 55-58, 65 and 72 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D.
PRIMARY EXAMINER